PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant: Stinson, J.	Examiner: Sweet, Thomas
Application No.: 10/721,702	Group Art Unit: 3738
Filed: November 25, 2003	Docket: 792-64 DIV II
For: BIOABSORBABLE ENDOPROSTHESIS HAVING ELONGATE AXIAL RESERVOIR FOR BY-PRODUCT COLLECTION	Dated: February 6, 2008

Confirmation No.: 6272

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Dated: February 6, 2008

Signature: Barbara Thomas

RESPONSE TO THE NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

Sir:

The Appellant has received a Notification of a Non-Compliant Appeal Brief, dated January 18, 2008. This Response correctly contains a concise statement for each ground of the rejection on appeal. The Final Office Action of February 20, 2007 listed claims 30, 44, 46, 50-59 and 76-84 as being finally rejected. The Final Office Action, however, did not list claims 45 and 47-49 as being withdrawn. This was in error. The Amendment And Response Pursuant to 37 C.F.R. §1.111, dated November 21, 2006, which was a communication filed immediately preceding the issuance of the Final Office Action, listed claims 45 and 47-49 as being withdrawn. Accordingly, it is respectfully submitted that claims 45 and 47-49 as still pending in this case, but are withdrawn. The Appellant has modified Section III accordingly and has modified sections VI and VII to exclude the withdrawn claims.

I. Real Party In Interest

The real party in interest is Schneider (USA), Inc., the assignee of the entire right, title and interest in and to Application No. 09/556,671.

II. Related Appeals and Interferences

No related appeals or interferences are known to the Appellant or the Appellant's legal representative which will directly affect or be directly affected by or have bearing on the Board's decision in this appeal.

III. Status of Claims

Claims 30, 44-59 and 76-84 are presently pending in the application. Claims 45 and 47-49 are withdrawn. Claims 30, 44, 46, 50-59 and 76-84 stand as being finally rejected. These claims, i.e., claims 30, 44, 46, 50-59 and 76-84, are being appealed.

IV. Status of Amendments

In response to the final rejection mailed February 20, 2007, a Notice of Appeal was filed on June 14, 2007 without further amendments. In addition, no further amendments have been presented after the filing of this appeal.

V. Summary of Claimed Subject Matter

The present invention is directed to an endoprosthesis formed from a plurality of hollow bioabsorbable filaments. (Specification, page 14, second full paragraph, lines 1-7). Bioabsorbable filaments, including hollow bioabsorbable filaments, are not as strong as metallic filaments. (Specification, page 8, first fill paragraph, lines 1-5). Nevertheless, the bioabsorbable endoprosthesis of the present invention is configured to have the same or similar

radial strength to a stent made from stronger metallic filaments. (Specification, page 8, first fill paragraph, lines 5-8). The strength of the endoprosthesis of the present invention is achieved without the use of other stent structures, such a tubular main body supporting the filaments as present in the prior art. (Specification, page 18, second fill paragraph, lines 1-4).

The present invention as set forth independent claim 30 is directed to a bioabsorbable endoprosthesis. The endoprosthesis consists essentially of a plurality of elongate elements having an outer surface. (Specification, page 12, lines 2-3). The elements include a bioabsorbable polymer adapted to undergo degradation *in vivo*. (Specification, page 9, lines 15-16). The elements also include an elongate, axially extending reservoir portion adapted to collect a by-product of the degradation of the bioabsorbable polymer. (Specification, page 9, lines 4-5). Desirably, the elements occupies a total element volume including a reservoir volume occupied by the at least one reservoir portion where the reservoir volume should be at least about ten percent of the total element volume. (Specification, page 10, lines 2-5).

Claim 81 depends from claim 30. This dependent claim sets forth the number of filaments and their thickness that may be used for the endoprosthesis of claim 30. Desirably, the number of elements, N, is equal to about $(D/(0.022D + 0.17)) \pm 4$ filaments, where D, in mm, is the free state diameter of the endoprosthesis. (Specification, page 9, lines 22-23). Desirably, the elongate elements have a thickness, t in mm, of about $(D/(1.8D + 15)) \pm 0.03$ mm, where D, in mm, is the free state diameter of the endoprosthesis. (Specification, page 9, lines 20-22).

The present invention as set forth independent claim 82 is directed to a braided bioabsorbable endoprosthesis. (Specification, page 8, lines 1-5). The bioabsorbable endoprosthesis comprises a plurality of elongate elements interbraided into a tubular, radially expandable structure. (*Id.*). The elongate elements have an outer surface and include a bioabsorbable polymer adapted to undergo degradation *in vivo*. (Specification, page 9, lines

15-16). The elements include an elongate, axially extending reservoir portion adapted to collect a by-product of the degradation of the bioabsorbable polymer. (Specification, page 9, lines 4-5). Each of the elements occupies a total element volume including a reservoir volume occupied by the at least one reservoir portion, and the reservoir volume is at least about ten percent of the total element volume. (Specification, page 10, lines 2-5). The number of elements, N, is equal to about $(D/(0.022D + 0.17)) \pm 4$ filaments, where D, in mm, is the free state diameter of the tubular structure. (Specification, page 9, lines 22-23). The elongate elements have a thickness, t in mm, of about $(D/(1.8D + 15)) \pm 0.03$ mm, where D, in mm, is the free state diameter of the tubular structure. (Specification, page 9, lines 20-22).

VI. Grounds of Rejection to be Reviewed on Appeal

The following grounds of rejection are to be reviewed on this Appeal:

I. Whether claims 30, 44, 46, 50-59 and 76-84 are anticipated under 35 U.S.C. §102(b) by U.S. Patent No. 5,500,013 to Buscemi et al.?

I. Whether claims 30, 44, 46, 50-59 and 76-84 are obvious under 35 U.S.C. §103(a) over U.S. Patent No. 5,500,013 to Buscemi et al.?

VII. Argument

I. Rejection under 35 U.S.C. §102(b) by U.S. Patent No. 5,500,013 to Buscemi et al.

Claims 30, 44, 46, 50-59 and 76-81

U.S. Patent No. 5,500,013 to Buscemi et al. (hereinafter "Buscemi") describes a biodegradable stent 10. (Buscemi, column 4, lines 8-9). The stent 10 includes a main body 11 and a plurality of fibers 18 disposed around the main body 11. (Buscemi, column 4, lines 16-18) (emphasis added). The fibers 18 are described as being annularly wound, braided or woven around the main body of the stent 10. (Buscemi, column 4, lines 32-44) (emphasis added). The fibers 18 may be hollow fibers having an outer diameter not exceeding 0.2 mm and having a wall thickness of 25 to 100 microns. (Buscemi, column 4, lines 7-48, column 4, lines 60-64).

Further, a film may be used to cover the fibers 18 to form a cover or may be used to line the inner surface of the main body 11 to form a liner. (Buscemi, column 5, lines 1-18). Thus, the main body 11 of Buscemi is not "basically an inner covering", as set forth in the Advisory Action, because Buscemi specifically describes that if an inner covering is desired that it must be added in addition to its main body 11.

Thus, Buscemi fails to disclose a bioabsorbable endoprosthesis as set forth in independent claim 30, which consists essentially of a plurality of elongate elements having an outer surface, the elements including a bioabsorbable polymer adapted to undergo degradation *in vivo*, the elements including an elongate, axially extending reservoir portion adapted to collect a by-product of the degradation of the bioabsorbable polymer; wherein the elements occupies a total element volume including a reservoir volume occupied by the at least one reservoir portion, and the reservoir volume is at least about ten percent of the total element volume.

In other words, Buscemi fails to disclose that its stent 10 may consist essentially of fibers 18. The main body 11 of the stent 10 of Buscemi is an essential feature of Buscemi's stent 10, and the main body may not be removed from the stent 10 without destroying the intent, function and purpose of Buscemi's stent 10. Further, the main body 11 of Buscemi is not a mere inner covering as alleged by the Examiner because where an inner covering is desired Buscemi specifically adds the inner covering to the main body 11 of its stent. Such specific teachings of Buscemi may not be properly ignored when formulating a *prima facie* case of anticipation.

Moreover, Buscemi clearly shows the main body 11 of the stent 10 is an essential feature of Buscemi. For example as depicted in Figure 1, the fibers 18 (i) are clearly disposed over only portions of the main body 11 and are not disposed over apertures 14, 26 of the main body 11; (ii) are clearly not interconnected with one another; and (iii) each have opposed ends separated by a gap over the apertures 14, 26. With such a structure, the fibers 18 do not form a tubular endoprosthesis by themselves without the necessary main body 11, especially when fibers are to be absent from the open apertures 14, 26. Exclusion of the fibers 18 from the open apertures 14, 26 of the main body 11 would make the fibers 18 inoperable as a endoprosthesis when the main body 11 is removed because the fibers would not form a self-supporting tubular

endoprosthesis, regardless whether the fibers 18 of Buscemi are annularly wound, braided or woven.

For convenience of the Board, Figure 1 of Buscemi is reproduced below, as follows:

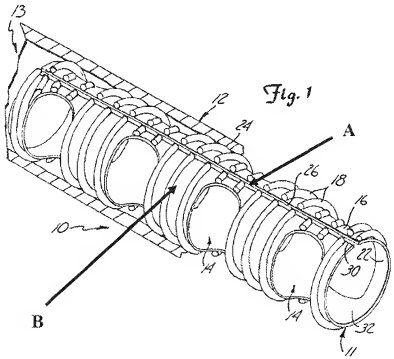
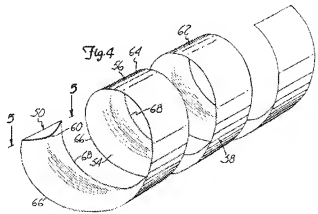


Fig. 1

The short truncated fibers 18 noted generally by vector "A" would clearly not form a tubular stent wall structure in the absence of the main body 11. Further, the fibers 18 noted generally by vector "B" would not form a tubular stent wall structure in the absence of the main body 11 because there would be no interconnection between the individual truncated fiber rings.

Thus, if the main body 11 was to be removed from the stent 10 of Figure 1, the remaining fibers 18 would not form an implantable structure because the fibers 18 would fail to provide a self-supporting open lattice tubular wall structure having sufficient mechanical integrity necessary to hold open a body lumen.

Further, when the main body 11 of Buscemi is not present, Buscemi fails to disclose that a plurality of braided fibers may be used to form a stent body. Indeed, Buscemi specifically teaches that a coiled stent 50 is to be used in the absence of the main body 11, as depicted in Figure 4, which is reproduced below for the convenience of the Board, as follows:



It should be noted that as depicted in the above Figure 4 of Buscemi, that the coil stent 50 does not have a plurality of elongate members for its stent, but only has one coiled member forming its stent. Further, the width of the coiled member is about 2 mm (Buscemi, column 6, lines 53-54) which is clearly outside of the width of the fibers of the present invention which vary from about 0.15 mm to about 0.6 mm (Specification, page 8, paragraph beginning with "In sum, the invention…", lines 7-8).

Thus, Buscemi fails to disclose a bioabsorbable stent having a plurality of bioabsorbable filaments or members in the absence of its main body 11. Moreover, the transitional phrase "consisting essentially of" in independent claim 30 excludes the main body 11 of Buscemi, as described below.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Hertz*, 190 U.S.P.Q. 461, 463 (CCPA 1976)

(emphasis in original); MPEP, §2111.3 (8th Ed., Rev. 5 (August 2006)). Further the MPEP states that "for the purposes of searching and applying prior art under U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to 'comprising'." (MPEP at §2111.3) (emphasis added).

During prosecution, the Examiner has taken the more expansive interpretation of the "consisting essentially of" phrase, i.e., "comprising". Appellant, however, respectfully submits that clear indications of the basic and novel characteristics of the present invention are present in the subject application such that the transitional phrase "consisting essentially of" limits the scope of the claims to exclude other structures, in particular the main body 11 of Buscemi.

The specification clearly describes the basic and novel features of the inventive stent having accelerated degradation achieved by filaments having a reservoir, as follows:

> **FIGS. 3a-3f illustrate cross-sections of a known member 10....The degradation rate nearer to the surface 14 of member 10 is relatively slower because pH level at the surface 14 is not substantially changes since acid degradation by-products are more readily flushed or diffused away.** (Specification page 13, paragraph beginning with "In comparison…", lines 1-3) (emphasis added)
>
> **[F]ilaments [of the present invention] ... advantageously provide accelerated degradation features compared to known materials. The filaments or elongate members have reservoir portions....** (Specification page 14, paragraph beginning with "FIGS. 3a-3f illustrate …", lines 1-12) (emphasis added)

Moreover, the specification clearly indicates that such filaments, i.e., filaments having hollow reservoirs, are to be used to form the stent to the exclusion of other stent structures, as follows:

> **The tubular and self-expandable body or structure form by the interwoven filaments 20, 30, 40 is a primary**

> **prosthetically-functional structure of stent 10, and for this reason the device can be considered to substantially consist of this structure to the exclusion of other structures.** (Specification page 18, paragraph beginning with "The tubular and ...", lines 1-4) (emphasis added)

Furthermore, the specification also indicates features that do not materially affect the basic and scope characteristics of the claimed invention include those which may be used for aiding implantation of the stent, as follows:

> **However, ... features which enhance or cooperate with the tubular stent and the self-expandable structure or which facilitate the implantation of the structure [may be included, for example] ... radiopaque markers[,] ... a covering or additional interwoven filaments, ... collapsing threads or other structures to facilitate repositioning and removal of the stent. Stents of these-types nonetheless still substantially consist of the tubular and self-expandable structure formed by the interwoven filaments 20, 30, 40.** (Specification page 18, paragraph beginning with "The tubular and ...", lines 4-13) (emphasis added)

Thus, the specification clearly sets forth the basic and novel characteristics of the present invention. Such basic and novel characteristics exclude the main body 11 of Buscemi. Further, the reliance on *In re Herz* for an "expansive" reading of "consisting essentially of" is not appropriate in the present matter.

In *In re Herz* the court noted that the specification of that contested application described that its composition could include additives, such as dispersants. *In re Hertz*, at 463. The court ruled that the "consisting essentially of" language of the claim would not limit its scope to exclude such additives. Thus, in *In re Herz*, the court ruled that the "consisting essentially of" language in the claims is not a substitute to the teaching of the specification. In the *In re Herz* case, that applicant could not exclude matter from the claims by the "consisting

essentially of" language where specification taught that its compositions may specifically include the same matter.

In the present application, the specification clearly teaches that a main body, such as the main body 11 of Buscemi, is not to be included with the limitation of "consisting essentially of". Thus, the subject specification clearly sets forth the basic and novel characteristics of the invention to the exclusion of the required main body 11 of the Buscemi stent 10.

Therefore, the final office action does not properly apply the correct standard to the "consisting essentially of" phrase in the independent claim 30 when considering the applied art. The "consisting essentially of" limitation in the independent claim 30 is a transitional phrase that limits the scope of the claim. As such, this transitional phrase is used to exclude other stent structures, such as the main body stent structure of Buscemi, from the scope of the independent claim 30.

Thus, Buscemi fails to disclose the bioabsorbable endoprosthesis as set forth in independent claim 30. Therefore, independent claim 30 and all claims dependent therefrom are patentably distinct over Buscemi under 35 U.S.C. §102(b).

Claims 82-84

Buscemi describes a biodegradable stent 10. (Buscemi, column 4, lines 8-9). The stent 10 includes a main body 11 and a plurality of fibers 18 disposed around the main body 11. (Buscemi, column 4, lines 16-18) (emphasis added). The fibers 18 are described as being annularly wound, braided or woven around the main body of the stent 10. (Buscemi, column 4, lines 32-44) (emphasis added). The fibers 18 may be hollow fibers having an outer diameter not exceeding 0.2 mm and having a wall thickness of 25 to 100 microns. (Buscemi, column 4, lines 7-48, column 4, lines 60-64).

The main body 11 includes a slot 26. The slot 26 permits compression of the diameter of the main body 11. (Buscemi , column 5, lines 54-56). When the slot 26 is at its widest configuration, the stent 10 is at a maximum or implanted diameter. (*Id.*). Thus, the main body 11 is radially extensible so that its diameter may be reduced for delivery to a body lumen and so that its diameter may be maximized to support the body lumen after implantation.

Buscemi fails to disclose a bioabsorbable endoprosthesis as set forth in independent claim 82, which comprises a plurality of elongate elements interbraided into a tubular, radially expandable structure, each of the elongate elements having an outer surface, the elements including a bioabsorbable polymer adapted to undergo degradation *in vivo*, the elements including an elongate, axially extending reservoir portion adapted to collect a by-product of the degradation of the bioabsorbable polymer; wherein the each of the elements occupies a total element volume including a reservoir volume occupied by the at least one reservoir portion, and the reservoir volume is at least about ten percent of the total element volume; the number of elements, N, is equal to about $(D/(0.022D + 0.17)) \pm 4$ filaments, where D, in mm, is the free state diameter of the tubular structure; and the elongate elements have a thickness, t in mm, of about $(D/(1.8D + 15)) \pm 0.03$ mm, where D, in mm, is the free state diameter of the tubular structure.

Buscemi is silent as to the relationship of number of filaments and their thickness for a bioabsorbable endoprosthesis. This relationship is important to the endoprosthesis of the present invention because it is the plurality of elongate members that provide support to a bodily lumen. It is the main body 11 of stent 10 and not the fibers 18 of Buscemi that provide the support to the bodily lumen.

The subject application specifically teaches that the braided bioabsorbable elements should have similar strength to that of a metallic stent even though the bioabsorbable elements have lower tensile strength of typical metals forming a metallic stent. (Specification, page 8,

first full paragraph). Indeed, the subject application specifically teaches that the braided bioabsorbable elements themselves should have sufficient strength to hold open a body lumen, as follows:

> **The polymeric braided stents should have sufficient radial strength similar to metallic stents and should have the required mechanical properties capable of bracing open endoluminal strictures.** (Specification, page 8, first full paragraph, lines 7-8).
>
> **The first set of filaments and second set of filaments act upon one another to create an outwardly directed radial force sufficient to implant the stent in a body vessel upon deployment from a delivery device.** (Specification, page 12, lines 7-9).

Moreover, the subject application specifically describes the necessary radial forces useful, as follows:

> **The stent may have an outside diameter when in the second radially expanded state and the stent may exert an outwardly directed radial force at one half of the outside diameter of from about 40 grams to about 300 grams.** (Specification, page 12, lines 19-21).

The number of filaments and the filament thickness are set forth as claimed to provide, *inter alia*, a braided stent of bioabsorbable filaments with such a desirable radial force. (Specification, page 8, last paragraph, lined 1-5; page 9, lines 20-23).

Thus, Buscemi fails to disclose the bioabsorbable endoprosthesis as set forth in independent claim 82 because, *inter alia*, Buscemi is silent on the relationship among filament thickness, filament number and radial forces resulting from braiding a specific number filaments having specifically defined thicknesses.

As Buscemi is silent on the relationship of the number of filaments and the filament thickness as claimed, the Examiner must then properly apply an inherency argument to the missing descriptive matter of Buscemi. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Crown Oper. Int'l Inc. v. Solutia Inc.*, 289 F.3d 1367, 62 U.S.P.Q.2d 1917 (Fed. Cir. 2002). Further, inherency may not be established by probabilities or possibilities, and the mere fact that a certain thing may result from a given set of circumstances is not sufficient for a *prima facie* case of anticipation. *Scaltech Inc. v. Retec/Tetra L.L.C.*, 153 F.3d 1193, 51 U.S.P.Q.2d 1055 (Fed. Cir. 1999). Occasional results are not inherent. *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1365, 52 U.S.P.Q.2d 1303, 1306 (Fed. Cir. 1999).

Therefore, Buscemi fails to disclose, either expressly or inherently, the bioabsorbable endoprosthesis as set forth in independent claim 82. Accordingly, independent claim 82 and all claims dependent therefrom are not anticipated by Buscemi under 35 U.S.C. §102(b).

II. Rejection under 35 U.S.C. §103(a) over U.S. Patent No. 5,500,013 to Buscemi et al.

Claims 30, 44, 46, 50-59 and 76-80

U.S. Patent No. 5,500,013 to Buscemi et al. (hereinafter "Buscemi") describes a biodegradable stent 10. (Buscemi, column 4, lines 8-9). The stent 10 includes a main body 11 and a plurality of fibers 18 disposed around the main body 11. (Buscemi, column 4, lines 16-18) (emphasis added). The fibers 18 are described as being annularly wound, braided or woven around the main body of the stent 10. (Buscemi, column 4, lines 32-44) (emphasis added).

The fibers 18 may be hollow fibers having an outer diameter not exceeding 0.2 mm and having a wall thickness of 25 to 100 microns. (Buscemi, column 4, lines 7-48, column 4, lines 60-64).

Further, a film may be used to cover the fibers 18 to form a cover or may be used to line the inner surface of the main body 11 to form a liner. (Buscemi, column 5, lines 1-18). Thus, the main body 11 of Buscemi is not "basically an inner covering", as set forth in the Advisory Action, because Buscemi specifically describes that if an inner covering is desired that it must be added in addition to its main body 11.

Thus, Buscemi fails to teach or suggest a bioabsorbable endoprosthesis as set forth in independent claim 30, which consists essentially of a plurality of elongate elements having an outer surface, the elements including a bioabsorbable polymer adapted to undergo degradation *in vivo*, the elements including an elongate, axially extending reservoir portion adapted to collect a by-product of the degradation of the bioabsorbable polymer; wherein the elements occupies a total element volume including a reservoir volume occupied by the at least one reservoir portion, and the reservoir volume is at least about ten percent of the total element volume.

In other words, Buscemi fails to teach or suggest that its stent 10 may consist essentially of fibers 18. The main body 11 of the stent 10 of Buscemi is an essential feature of Buscemi's stent 10, and the main body may not be removed from the stent 10 without destroying the intent, function and purpose of Buscemi's stent 10. Further, the main body 11 of Buscemi is not a mere inner covering as alleged by the Examiner because where an inner covering is desired Buscemi specifically adds the inner covering to the main body 11 of its stent. Such specific teachings of Buscemi may not be properly ignored when formulating a *prima facie* case of obviousness.

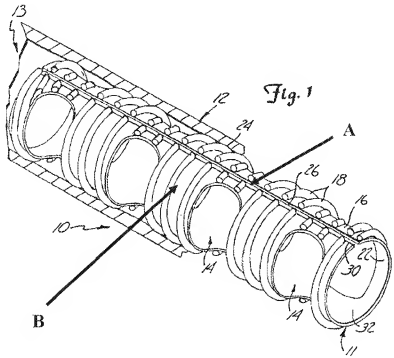
In establishing a *prima facie* case of obviousness, the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230

U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* It is only through hindsight reconstruction does the Examiner attempt to reach the present invention through the teachings of Buscemi. It is also well established, however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness, and any attempt at hindsight reconstruction using Appellant's disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Moreover, Buscemi clearly shows the main body 11 of the stent 10 is an essential feature of Buscemi. For example as depicted in Figure 1, the fibers 18 (i) are clearly disposed over only portions of the main body 11 and are not disposed over apertures 14, 26 of the main body 11; (ii) are clearly not interconnected with one another; and (iii) each have opposed ends separated by a gap over the apertures 14, 26. With such a structure, the fibers 18 do not form a tubular endoprosthesis by themselves without the necessary main body 11, especially when fibers are to be absent from the open apertures 14, 26. Exclusion of the fibers 18 from the open apertures 14, 26 of the main body 11 would make the fibers 18 inoperable as a endoprosthesis when the main body 11 is removed because the fibers would not form a self-supporting tubular endoprosthesis, regardless whether the fibers 18 of Buscemi are annularly wound, braided or woven.

An inoperable reference, such as the stent 10 of Buscemi without its main body 11, cannot form a basis for a *prima facie* case of obviousness. *In re Gordon et al.*, 221 U.S.P.Q. 1125, 1127 (CAFC 1984). Indeed, such an inoperable device is a teaching away from the present invention. *Id.*

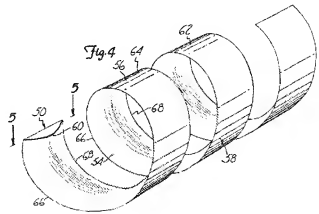
For convenience of the Board, Figure 1 of Buscemi is reproduced below, as follows:



The short truncated fibers 18 noted generally by vector "A" would clearly not form a tubular stent wall structure in the absence of the main body 11. Further, the fibers 18 noted generally by vector "B" would not form a tubular stent wall structure in the absence of the main body 11 because there would be no interconnection between the individual truncated fiber rings.

Thus, if the main body 11 was to be removed from the stent 10 of Figure 1, the remaining fibers 18 would not form an implantable structure because the fibers 18 would fail to provide a self-supporting open lattice tubular wall structure having sufficient mechanical integrity necessary to hold open a body lumen. Such an inoperable device as proposed by the Examiner cannot form a basis for a *prima facie* case of obviousness. *In re Gordon et al.*, 221 U.S.P.Q. 1125, 1127 (CAFC 1984).

Further, when the main body 11 of Buscemi is not present, Buscemi fails to teach or suggest that a plurality of braided fibers may be used to form a stent body. Indeed, Buscemi specifically teaches that a coiled stent 50 is to be used in the absence of the main body 11, as depicted in Figure 4, which is reproduced below for the convenience of the Board, as follows:



It should be noted that as depicted in the above Figure 4 of Buscemi, that the coil stent 50 does not have a plurality of elongate members for its stent, but only has one coiled member forming its stent. Further, the width of the coiled member is about 2 mm (Buscemi, column 6, lines 53-54) which is clearly outside of the width of the fibers of the present invention which vary from about 0.15 mm to about 0.6 mm (Specification, page 8, paragraph beginning with "In sum, the invention...", lines 7-8).

Thus, Buscemi fails to teach or suggest a bioabsorbable stent having a plurality of bioabsorbable filaments or members in the absence of its main body 11. Moreover, the transitional phrase "consisting essentially of" in independent claim 30 excludes the main body 11 of Buscemi, as described below.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Hertz*, 190 U.S.P.Q. 461, 463 (CCPA 1976)

(emphasis in original); MPEP, §2111.3 (8th Ed., Rev. 5 (August 2006)). Further the MPEP states that "for the purposes of searching and applying prior art under U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to 'comprising'." (MPEP at §2111.3) (emphasis added).

During prosecution, the Examiner has taken the more expansive interpretation of the "consisting essentially of" phrase, i.e., "comprising". Appellant, however, respectfully submits that clear indications of the basic and novel characteristics of the present invention are present in the subject application such that the transitional phrase "consisting essentially of" limits the scope of the claims to exclude other structures, in particular the main body 11 of Buscemi.

The specification clearly describes the basic and novel features of the inventive stent having accelerated degradation achieved by filaments having a reservoir, as follows:

> **FIGS. 3a-3f illustrate cross-sections of a known member 10….The degradation rate nearer to the surface 14 of member 10 is relatively slower because pH level at the surface 14 is not substantially changes since acid degradation by-products are more readily flushed or diffused away.** (Specification page 13, paragraph beginning with "In comparison…", lines 1-3) (emphasis added)
>
> **[F]ilaments [of the present invention] … advantageously provide accelerated degradation features compared to known materials. The filaments or elongate members have reservoir portions….** (Specification page 14, paragraph beginning with "FIGS. 3a-3f illustrate …", lines 1-12) (emphasis added)

Moreover, the specification clearly indicates that such filaments, i.e., filaments having hollow reservoirs, are to be used to form the stent to the exclusion of other stent structures, as follows:

> **The tubular and self-expandable body or structure form by the interwoven filaments 20, 30, 40 is a primary**

> **prosthetically-functional structure of stent 10, and for this reason the device can be considered to substantially consist of this structure to the exclusion of other structures.** (Specification page 18, paragraph beginning with "The tubular and …", lines 1-4) (emphasis added)

Furthermore, the specification also indicates features that do not materially affect the basic and scope characteristics of the claimed invention include those which may be used for aiding implantation of the stent, as follows:

> **However, … features which enhance or cooperate with the tubular stent and the self-expandable structure or which facilitate the implantation of the structure [may be included, for example] … radiopaque markers[,] … a covering or additional interwoven filaments, … collapsing threads or other structures to facilitate repositioning and removal of the stent. Stents of these-types nonetheless still substantially consist of the tubular and self-expandable structure formed by the interwoven filaments 20, 30, 40.** (Specification page 18, paragraph beginning with "The tubular and …", lines 4-13) (emphasis added)

Thus, the specification clearly sets forth the basic and novel characteristics of the present invention. Such basic and novel characteristics exclude the main body 11 of Buscemi. Further, the reliance on *In re Herz* for an "expansive" reading of "consisting essentially of" is not appropriate in the present matter.

In *In re Herz* the court noted that the specification of contested application described that its composition could include additives, such as dispersants. *In re Hertz*, at 463. The court ruled that the "consisting essentially of" language of the claim would not limit its scope to exclude such additives. Thus, in *In re Herz*, the court ruled that the "consisting essentially of" language in the claims is not a substitute to the teaching of the specification. In the *In re Herz* case, that applicant could not exclude matter from the claims by the "consisting essentially of"

language where specification taught that its compositions may specifically include the same matter.

In the present application, the specification clearly teaches that a main body, such as the main body 11 of Buscemi, is not to be included with the limitation of "consisting essentially of". Thus, the subject specification clearly sets forth the basic and novel characteristics of the invention to the exclusion of the required main body 11 of the Buscemi stent 10.

Therefore, the final office action does not properly apply the correct standard to the "consisting essentially of" phrase in the independent claim 30 when considering the applied art. The "consisting essentially of" limitation in the independent claim is a transitional phrase that limits the scope of the independent claim 30. As such, this transitional phrase is used to exclude other stent structures, such as the main body stent structure of Buscemi, from the scope of the independent claim 30.

Thus, Buscemi fails to disclose, teach or suggest the bioabsorbable endoprosthesis as set forth in independent claim 30. Therefore, independent claim 30 and all claims dependent therefrom are patentably distinct over Buscemi under 35 U.S.C. §103(a).

Claim 81

Claim 81 depends from independent claim 30. Claim 81 sets forth criteria for the number of elements and their thickness. The number of filaments and the filament thickness are set forth as claimed to provide, *inter alia*, a stent of bioabsorbable filaments with such a desirable radial force. (Specification, page 8, last paragraph, lined 1-5; page 9, lines 20-23).

The subject application specifically teaches that a stent of bioabsorbable elements should have similar strength to that of a metallic stent even tough the bioabsorbable elements

have lower tensile strength of typical metals forming a metallic stent . (Specification, page 8, first full paragraph). Indeed, the subject application specifically teaches that the bioabsorbable elements themselves should have sufficient strength to hold open a body lumen, as follows:

> **The first set of filaments and second set of filaments act upon one another to create an outwardly directed radial force sufficient to implant the stent in a body vessel upon deployment from a delivery device.** (Specification, page 12, lines 7-9).

Moreover, the subject application specifically describes the necessary radial force useful, as follows:

> **The stent may have an outside diameter when in the second radially expanded state and the stent may exert an outwardly directed radial force at one half of the outside diameter of from about 40 grams to about 300 grams.** (Specification, page 12, lines 19-21).

Buscemi fails to teach or suggest a relationship among filament thickness, filament number and radial forces resulting from forming a stent from a specific number of filaments having specifically defined thicknesses; especially because Buscemi requires the use of the main body 11 to support a body vessel in direct contrast to the present invention.

Thus, claim 81 is patentably distinct over Buscemi under 35 U.S.C. §103(a).

Claims 82-84

Buscemi describes a biodegradable stent 10. (Buscemi, column 4, lines 8-9). The stent 10 includes a main body 11 and a plurality of fibers 18 disposed around the main body 11. (Buscemi, column 4, lines 16-18) (emphasis added). The fibers 18 are described as being annularly wound, braided or woven around the main body of the stent 10. (Buscemi, column 4, lines 32-44) (emphasis added). The fibers 18 may be hollow fibers having an outer diameter

not exceeding 0.2 mm and having a wall thickness of 25 to 100 microns. (Buscemi, column 4, lines 7-48, column 4, lines 60-64).

The main body 11 includes a slot 26. The slot 26 permits compression of the diameter of the main body 11. (Buscemi , column 5, lines 54-56). When the slot 26 is at its widest configuration, the stent 10 is at a maximum or implanted diameter. (*Id.*). Thus, the main body 11 is radially extensible so that its diameter may be reduced for delivery to a body lumen and so that its diameter may be maximized to support the body lumen after implantation.

Buscemi fails to teach or suggest a bioabsorbable endoprosthesis as set forth in independent claim 82, which comprises a plurality of elongate elements interbraided into a tubular, radially expandable structure, each of the elongate elements having an outer surface, the elements including a bioabsorbable polymer adapted to undergo degradation *in vivo*, the elements including an elongate, axially extending reservoir portion adapted to collect a by-product of the degradation of the bioabsorbable polymer; wherein the each of the elements occupies a total element volume including a reservoir volume occupied by the at least one reservoir portion, and the reservoir volume is at least about ten percent of the total element volume; the number of elements, N, is equal to about $(D/(0.022D + 0.17)) \pm 4$ filaments, where D, in mm, is the free state diameter of the tubular structure; and the elongate elements have a thickness, t in mm, of about $(D/(1.8D + 15)) \pm 0.03$ mm, where D, in mm, is the free state diameter of the tubular structure.

Buscemi is silent as to the relationship of number of filaments and their thickness for a bioabsorbable endoprosthesis. This relationship is important to the endoprosthesis of the present invention because it is the plurality of elongate members that provide support to a bodily lumen. It is the main body 11 of stent 10 and not the fibers 18 of Buscemi that provide the support to the bodily lumen.

The subject application specifically teaches that the braided bioabsorbable elements should have similar strength to that of a metallic stent even though the bioabsorbable elements have lower tensile strength of typical metals forming a metallic stent. (Specification, page 8, first full paragraph). Indeed, the subject application specifically teaches that the braided bioabsorbable elements themselves should have sufficient strength to hold open a body lumen, as follows:

> **The polymeric braided stents should have sufficient radial strength similar to metallic stents and should have the required mechanical properties capable of bracing open endoluminal strictures.** (Specification, page 8, first full paragraph, lines 7-8).
>
> **The first set of filaments and second set of filaments act upon one another to create an outwardly directed radial force sufficient to implant the stent in a body vessel upon deployment from a delivery device.** (Specification, page 12, lines 7-9).

Moreover, the subject application specifically describes the necessary radial forces useful, as follows:

> **The stent may have an outside diameter when in the second radially expanded state and the stent may exert an outwardly directed radial force at one half of the outside diameter of from about 40 grams to about 300 grams.** (Specification, page 12, lines 19-21).

The number of filaments and the filament thickness are set forth as claimed to provide, *inter alia*, a braided stent of bioabsorbable filaments with such a desirable radial force. (Specification, page 8, last paragraph, lined 1-5; page 9, lines 20-23).

Thus, Buscemi fails to teach or suggest the bioabsorbable endoprosthesis as set forth in independent claim 82 because, *inter alia*, Buscemi fails to teach or suggest any relationship

among filament thickness, filament number and radial forces resulting from braiding a specific number filaments having specifically defined thicknesses.

In establishing a *prima facie* case of obviousness, the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is only through hindsight reconstruction does the Examiner attempt to reach the present invention through the teachings of Buscemi because Buscemi fails to teach or suggest any relationship among filament thickness, filament number and radial forces resulting from braiding a specific number filaments having specifically defined thicknesses.

Without some teaching or suggestion in Buscemi regarding a relationship among filament thickness, filament number and radial forces resulting from braiding a specific number filaments having specifically defined thicknesses, it is only through hindsight reconstruction does the Examiner attempt to present a *prima facie* case of obviousness. It is also well established, however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness, and any attempt at hindsight reconstruction using Appellant's disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Thus, Buscemi fails to teach or suggest the bioabsorbable endoprosthesis as set forth in independent claim 82. Therefore, independent claim 82 and all claims dependent therefrom are patentably distinct.

Thus, for the reasons set forth herein, claims 30, 44, 46, 50-59 and 76-84 are patentably distinct over the applied references. Withdrawal of the rejection of claims 30, 44, 46, 50-59 and 76-84 is respectfully requested. Allowance of claims 30, 44, 46, 50-59 and 76-84 are further respectfully requested.

Furthermore, entry and allowance of the withdrawn claims 45 and 47-49 are respectfully requested.

Respectfully submitted,

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VIII. Claims Appendix

Claims 1.-29. (Canceled)

Claim 30. (Previously presented) A bioabsorbable endoprosthesis consisting essentially of:

a plurality of elongate elements having an outer surface, the elements including a bioabsorbable polymer adapted to undergo degradation *in vivo*, the elements including an elongate, axially extending reservoir portion adapted to collect a by-product of the degradation of the bioabsorbable polymer;

wherein the elements occupy a total element volume including a reservoir volume occupied by the at least one reservoir portion, and the reservoir volume is at least about ten percent of the total element volume.

Claims 31-43. (Canceled)

Claim 44. (Previously presented) The endoprosthesis of claim 30 wherein:

the reservoir portion comprises at least one axially extending core open to opposite ends of the element.

Claim 45. (Withdrawn) The endoprosthesis of claim 44 wherein:

the reservoir portion comprises a plurality of the axial extending cores.

Claim 46. (Previously presented) The endoprosthesis of claim 44 wherein:

a volume of the at least one axially extending core comprises from about ten percent to about 30 percent of the total element volume.

Claim 47. (Withdrawn) The endoprosthesis of claim 30 wherein:

the reservoir portion comprises at least one axially extending internal cavity recessed from the outer surface.

Claim 48. (Withdrawn) The endoprosthesis of claim 47 wherein:

the at least one cavity occupies a cavity volume ranging from about ten percent to about thirty percent of the total element volume.

Claim 49. (Withdrawn) The endoprosthesis of claim 47 wherein:

an average cross-sectional area of the cavity ranges from about ten percent to about thirty percent of a cross-sectional area of the elongate element.

Claim 50. (Previously presented) The endoprosthesis of claim 30 wherein:

the volume of the reservoir portion ranges from twenty percent to about forty percent of the total element volume.

Claim 51. (Previously presented) The endoprosthesis of claim 30 wherein:

the plurality of elongate elements is formed into a tubular, radially expandable structure.

Claim 52. (Previously presented) The endoprosthesis of claim 51 wherein:

the plurality of elongate elements comprises a first plurality of elements helically wound about an axis in a first direction, and a second plurality of elements helically wound about the axis in a second direction opposite the first direction to form multiple crossings with the first plurality of the elements.

Claim 53. (Previously presented) The endoprosthesis of claim 52 wherein:

the first and second pluralities of the elongate elements, at the multiple crossings, form crossing angles ranging from about 120 degrees to about 150 degrees.

Claim 54. (Previously presented) The endoprosthesis of claim 52 wherein:

the first and second pluralities of the elongate elements are interbraided.

Claim 55. (Previously presented) The endoprosthesis of claim 30 wherein:

the bioabsorbable polymer consists essentially of a polymer from the group consisting of: PLLA, PDLA, and their combinations.

Claim 56. (Previously presented) The endoprosthesis of claim 30 wherein:

the bioabsorbable polymer consists essentially of a polymer selected from the group consisting of: polylactide, polyglycolide, and their combinations.

Claim 57. (Previously presented) The endoprosthesis of claim 30 wherein:

the bioabsorbable polymer consists of a polymer selected from the group consisting of: polyglycolide, polygluconate, polydioxanone, and their combinations.

Claim 58. (Previously presented) The endoprosthesis of claim 30 wherein:

the plurality of elongate elements consists essentially of the bioabsorbable polymer.

Claim 59. (Previously presented) The endoprosthesis of claim 30 wherein:

the plurality of elongate elements is flexible.

Claims 60-75. (Canceled)

Claim 76. (Previously presented) The endoprosthesis of claim 51 wherein:

the number of elements, N, is equal to about $(D/(0.022D + 0.17)) \pm 4$ filaments, where D, in mm, is the free state diameter of the tubular structure.

Claim 77. (Previously presented) The endoprosthesis of claim 51 wherein:

the number of elements, N, is from about 10 to about 36 filaments.

Claim 78. (Previously presented) The endoprosthesis of claim 30 wherein:

the number of elements is from about 10 to about 36 filaments.

Claim 79. (Previously presented) The endoprosthesis of claim 51 wherein:

the structure has a radial force of from about 40 grams to about 300 grams at about one-half the diameter D, where D is the free state diameter of the tubular structure.

Claim 80. (Previously presented) The endoprosthesis of claim 51 wherein:

the elongate elements have a thickness, t in mm, of about $(D/(1.8D + 15)) \pm 0.03$ mm, where D, in mm, is the free state diameter of the tubular structure.

Claim 81. (Previously presented) The endoprosthesis of claim 30 wherein:

the number of elements, N, is equal to about $(D/(0.022D + 0.17)) \pm 4$ filaments, where D, in mm, is the free state diameter of the endoprosthesis; and the elongate elements have a thickness, t in mm, of about $(D/(1.8D + 15)) \pm 0.03$ mm, where D, in mm, is the free state diameter of the endoprosthesis.

Claim 82. (Previously presented) A bioabsorbable endoprosthesis comprising:

a plurality of elongate elements interbraided into a tubular, radially expandable structure, each of the elongate elements having an outer surface, the elements including a bioabsorbable polymer adapted to undergo degradation *in vivo*, the elements including an elongate, axially extending reservoir portion adapted to collect a by-product of the degradation of the bioabsorbable polymer;

wherein the each of the elements occupies a total element volume including a reservoir volume occupied by the at least one reservoir portion, and the reservoir volume is at least about ten percent of the total element volume;

the number of elements, N, is equal to about $(D/(0.022D + 0.17)) \pm 4$ filaments, where D, in mm, is the free state diameter of the tubular structure; and

the elongate elements have a thickness, t in mm, of about $(D/(1.8D + 15)) \pm 0.03$ mm, where D, in mm, is the free state diameter of the tubular structure.

Claim 83. (Previously presented) The endoprosthesis of claim 82 wherein:

the number of elements, N, is from about 10 to about 36 filaments.

Claim 84. (Previously presented) The endoprosthesis of claim 82 wherein:

the reservoir portion comprises at least one axially extending core open to opposite ends of the element.

IX. Evidence Appendix

There were no declarations or other evidence submitted during the prosecution of this application.

X. Related Proceedings Appendix

None